(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 527 792 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
04.05.2005 Bulletin 2005/18

(51) Int Cl.[7]: **A61M 5/142**

(21) Application number: **03024626.8**

(22) Date of filing: **27.10.2003**

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LU MC NL PT RO SE SI SK TR
Designated Extension States:
AL LT LV MK

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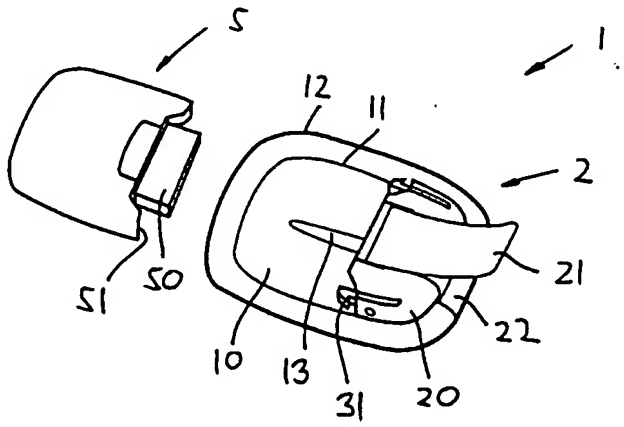
(54) Medical injection device mountable to the skin

(57) A medical device is provided comprising a transdermal access unit and a reservoir unit. The transdermal access unit comprises transdermal access means for transporting a fluid through a skin portion of a subject, and a mounting surface adapted for application to the skin of the subject. The reservoir unit comprises a reservoir adapted to contain a fluid drug, the reservoir comprising an outlet means allowing the transdermal access means to be arranged in fluid communication with an interior of the reservoir, and expelling means for expelling a fluid drug out of the reservoir and through the skin of the subject via the transdermal access means. The transdermal access unit and the reservoir unit further comprise releasable mating coupling means allowing the reservoir unit to be secured to the transdermal access unit in the situation of use. By this arrangement a two-unit system is provided which can be used in a convenient and cost-effective manner.

Fig. 1



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Description

[0001] The present invention generally relates to devices which are adapted for application to a skin surface of a subject and comprise fluid introduction means such as needles or needle-like members for introduction of a fluid through the skin of the subject. In specific aspects, the invention relates to such devices comprising a needle adapted for insertion at a selected site within the body of a subject for subcutaneous, intravenous, intramuscular or intradermal delivery of a drug to the subject, the needle also being adapted for connection to means for delivery of a drug through the needle, as well as to devices comprising needle-formed sensors.

BACKGROUND OF THE INVENTION

[0002] In the disclosure of the present invention reference is mostly made to the treatment of diabetes by injection or infusion of insulin, however, this is only an exemplary use of the present invention.

[0003] Portable drug delivery devices for delivering a drug to a patient are well known and generally comprise a reservoir adapted to contain a liquid drug and having an outlet in fluid communication with a hollow infusion needle, as well as expelling means for expelling a drug out of the reservoir and through the skin of the subject via the hollow needle. Such devices are often termed infusion pumps.

[0004] Basically, infusion pumps can be divided into two classes. The first class comprises infusion pumps which are relatively expensive pumps intended for 3-4 years use, for which reason the initial cost for such a pump often is a barrier to this type of therapy. Although more complex than traditional syringes and pens, the pump offer the advantages of continuous infusion of insulin, precision in dosing and optionally programmable delivery profiles and user actuated bolus infusions in connections with meals.

[0005] Addressing the above problem, several attempts have been made to provide a second class of drug infusion devices that are low in cost and convenient to use. Some of these devices are intended to be partially or entirely disposable and may provide many of the advantages associated with an infusion pump without the attendant cost and inconveniencies, e.g. the pump may be prefilled thus avoiding the need for filling or refilling a drug reservoir. Examples of this type of infusion devices are known from US patents 4,340,048 and 4,552,561 (based on osmotic pumps), US patent 5,858,001 (based on a piston pump), US patent 6,280,148 (based on a membrane pump), US patent 5,957,895 (based on a flow restrictor pump (also know as a bleeding hole pump)), US patent 5,527,288 (based on a gas generating pump), or US patent 5,814,020 (based on a swellable gel) which all in the last decades have been proposed for use in inexpensive, primarily disposable drug infusion devices, the cited documents being incorporated by reference.

[0006] The disposable pumps generally comprises a skin-contacting mounting surface adapted for application to the skin of a subject by adhesive means, and with the infusion needle arranged such that in a situation of use it projects from the mounting surface to thereby penetrate the skin of the subject, whereby the place where the needle penetrates the skin is covered while the appliance is in use. The infusion needle may be arranged to permanently project from the mounting surface such that the needle is inserted simultaneously with the application of the infusion pump, this as disclosed in US patents 2,605,765, 4,340,048 and in EP 1 177 802, or the needle may be supplied with the device in a retracted state, i.e. with the distal pointed end of the needle "hidden" inside the pump device, this allowing the user to place the pump device on the skin without the possibility of observing the needle, this as disclosed in US patents 5,858,001 and 5,814,020. In addition to pumps, alternative means for transporting a fluid drug may be used, e. g. iontophoresis as discussed below.

[0007] Although it can be expected that the above described second class of fully or partly disposable infusion devices can be manufactured considerably cheaper than the traditional durable infusion pump, they are still believed to be too expensive to be used as a real alternative to traditional infusion pumps for use on an every-day basis.

[0008] Before turning to the disclosure of the present invention, a different type of device relying on the insertion of a needle or needle-like structure will be described.

[0009] Although drug infusion pumps, either disposable or durable, may provide convenience of use and improved treatment control, it has long been an object to provide a drug infusion system for the treatment of e.g. diabetes which would rely on closed loop control, i.e. being more or less fully automatic, such a system being based on the measurement of a value indicative of the condition treated, e.g. the blood glucose level in case of insulin treatment of diabetes.

[0010] A given monitor system for measuring the concentration of a given substance may be based on invasive or non-invasive measuring principles. An example of the latter would be a non-invasive glucose monitor arranged on the skin surface of a patient and using near-IR spectroscopy, however, the present invention is concerned with the introduction of a transcutaneous device such as a needle-formed sensor element.

[0011] The sensor may be placed subcutaneously being connected to external equipment by wiring or the substance (e.g. fluid) to be analysed may be transported to an external sensor element, both arrangements requiring the placement of a subcutaneous component (e. g. small catheter or tubing), the present invention addressing both arrangements. However, for simplicity the term "sensor" is used in the following for both types of elements introduced into the subject.

DISCLOSURE OF THE INVENTION

[0012] Having regard to the above-identified problems, it is an object of the present invention to provide a skin mountable drug delivery device or system and components therefore, which allow such a device or system to be used in a convenient and cost-effective manner. The configuration of the system should contribute in providing a medical delivery means which allows for easy and swift operation yet being reliable in use.

[0013] Thus, corresponding to a first aspect, a medical device comprising a transdermal access unit and a reservoir unit is provided, wherein the transdermal access unit comprises transdermal access means for transporting a fluid through a skin portion of a subject, and a mounting surface adapted for application to the skin of the subject. The reservoir unit comprises a reservoir adapted to contain a fluid drug, the reservoir comprising an outlet means allowing the transdermal access means to be arranged in fluid communication with an interior of the reservoir, and expelling means for, in a situation of use, expelling a fluid drug out of the reservoir and through the skin of the subject via the transdermal access means. The transdermal access unit and the reservoir unit further comprise releasable mating coupling means allowing the reservoir unit to be secured to the transdermal access unit in the situation of use.

[0014] The term "transdermal" covers all forms of administration in which a fluid is transported through a portion of the skin, e.g. intradermal or subcutaneous administration.

[0015] The transdermal access means may be in the form of one or more hollow infusion needles, e.g. a single needle or an array of micro-needles, a jet injection means or electrodes allowing an ionic agent to permeate from a predetermined site on the surface of skin into the subcutaneous tissue of the subject by using the principle of iontophoresis. For a more thorough discussion of iontophoresis reference is made to US patent 6,622,037 hereby incorporated by reference. Depending on the nature of the transdermal access means the expelling means may be of different configuration. For example, when one or more hollow infusion needles are used, the expelling means may be arranged to force or suck the fluid drug from the reservoir, whereas in the case of iontophoresis the expelling means would be means for applying a current over a set of electrodes, i. e. "driving" means.

[0016] Thus, corresponding to a specific aspect, a medical device, comprising a needle unit and a reservoir unit is provided, wherein the needle unit comprises a needle having a pointed end adapted to penetrate the skin of a subject, and a mounting surface adapted for application to the skin of the subject. The reservoir unit comprises a reservoir adapted to contain a liquid drug, the reservoir comprising an outlet means allowing the needle to be arranged in fluid communication with an interior of the reservoir, expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the pointed end of the needle. Typically, the needle will be a hollow infusion needle. The needle unit and the reservoir unit further comprise releasable mating coupling means allowing the reservoir unit to be secured to the needle unit in the situation of use. Such a medical device comprising two units may also be considered a medical system.

[0017] By the above arrangements one of the units can be exchanged with a new or different unit yet allowing the other unit to be re-used, thereby lengthening the operational life of the re-used unit. More specifically, the present invention provides a device in which the components providing the interface with the user is incorporated in a first unit whereas the components providing the drug delivery *per se* is incorporated in a second unit, this allowing the combined components to be exchanged in a simple, reliable and user-friendly way.

[0018] For example, the reservoir unit may be provided with an amount of drug and a delivery pump comprising an energy source allowing the drug to be delivered over e.g. 10 days, whereas the needle unit may be provided with a needle unit and an adhesive surface on the mounting surface having an expected (or recommended) operational life of 2 days, this allowing the reservoir unit to be used with 5 needle units over a period of 10 days, this considerably lowering the total costs of using the combined device. The reservoir may be pre-filled or adapted to be filled one or more times.

[0019] On the other hand, a needle unit may be provided with a needle (e.g. a soft cannula) and adhesive means (e.g. of the type used for attaching colostomy bags) allowing the needle unit to be mounted and used over an extended period of time, the reservoir unit having a shorter expected operational life, e.g. when relatively large amounts of drugs have to be infused. Alternatively, different reservoir units with different types of drugs may be used in combination with such a "long-term" mounted needle unit.

[0020] For ease of use, the fluid communication between the needle and the reservoir may be established when the needle unit and the reservoir unit are secured to each other, just as the expelling means may be activated when the needle unit and the reservoir unit are secured to each other and de-activated when the units are released from each other. Indeed, one or both of the operations may also be performed manually by the user.

[0021] In an exemplary embodiment the expelling means comprises a pump having an inlet means adapted to be arranged in fluid communication with the outlet means of the reservoir, and an outlet means adapted to be arranged in fluid communication with the needle, thereby allowing the needle to be arranged in fluid communication with the interior of the reservoir. By such an arrangement the pump will serve as a suction pump drawing drug from the reservoir which consequently will have to be either collapsible or vented in case a non-collapsible reservoir is used.

[0022] In order to provide an initially sterile flow path through the pump, the flow path may be arranged between the inlet and outlet means such that the inlet and outlet means seals the interior of the pump and thereby the flow path in an initial sterile state. By this arrangement it will not be necessary to provide the reservoir unit as an entirely sterile unit - indeed, the drug will have to be provided in a sterile state.

[0023] In an exemplary embodiment, the reservoir unit is transformable from an initial condition in which there is no fluid communication between the pump and the reservoir to a non-reversible operating condition in which fluid communication is established between the inlet means of the pump and the outlet means of the reservoir when the pump unit is secured to a needle unit for the first time. By this arrangement it is avoided that undesired matter is introduced into the reservoir during re-connection between the pump and the reservoir.

[0024] To secure a clean connection between the pump and the reservoir, a separate connection needle may be arranged within the interior of the pump in the initial condition. Such a needle may comprise a pointed inlet end and an outlet, whereas the inlet means of the pump and the outlet means of the reservoir may be in the form of two needle- penetratable septa. By this arrangement the pointed end of the connection needle can be moved through the two septa and thus between the initial condition and an operating condition in which fluid communication is established between the interior of the reservoir and the interior of the pump via the connection needle, the outlet of the connection needle being arranged in the flow path. Advantageously the connection needle is moved between its two positions as the reservoir unit is connected to a needle unit for the first time. Correspondingly during such a first connection two fluid communications will be established (between the needle of the needle unit and the pump, and between the pump and the reservoir), whereas during subsequent connections only a single new fluid communication will be established (between the needle of the needle unit and the pump).

[0025] In an exemplary embodiment the needle comprises a first needle portion having a pointed distal end, and a second needle portion in fluid communication with the first needle portion and having a second end. Advantageously the second end of the needle is pointed and the outlet means of the pump comprises a needle-penetratable septum allowing a fluid communication to be established between the second end of the needle and the interior of the pump, preferably as the two units are connected to each other.

[0026] Correspondingly, in a general aspect the present invention provides a pump having an inlet means adapted to be arranged in fluid communication with a fluid supply, and an outlet means, the pump comprising an internal flow path arranged between the inlet and outlet means, the inlet and outlet means sealing the interior of the pump and thereby the flow path in an initial sterile condition, wherein a fluid connection means is arranged within the interior of the pump in the initial condition, the fluid connection means comprising an inlet end and an outlet, whereby the fluid connection means is arranged to be moved between the initial condition and to an operating condition in which the inlet end projects from the pump inlet means, whereby a fluid communication can be established between the fluid supply and the interior of the pump via the fluid connection means and with the outlet of the fluid connection means being arranged in the flow path.

[0027] As mentioned above, the needle unit may be supplied with the needle projecting from the mounting surface, however, to limit the risk of accidental needle injuries, the pointed end of the needle is advantageously moveable between an initial position in which the pointed end is retracted relative to the mounting surface, and an extended position in which the pointed end projects relative to the mounting surface. Depending on the intended method of mounting the device on the user, the needle may be moved between the two positions as the two units are connected to each, as would be appropriate in case the needle unit is mounted on the skin of the user before the reservoir unit is connected. However, in case the two units are intended to be connected to each other before assembled units are mounted on the skin of the user, the needle unit advantageously comprises user-actuatable actuation means for moving the pointed end of the needle between the initial and the second position.

[0028] To prevent inadvertent actuation of the needle before the two units are assembled, the needle unit may comprise means for blocking the actuation means, the blocking means being released when the needle unit and the reservoir unit are secured to each other, thereby allowing the actuation means to be actuated.

[0029] To further reduce the likelihood of needle injuries, the pointed end of the needle may be moveable between the extended position in which the pointed end projects relative to the mounting surface, and a retracted position in which the pointed end is retracted relative to the mounting surface. Correspondingly, the combined device may comprise user-actuatable retraction means for moving the pointed end of the needle between the extended and the retracted position when the retraction means is actuated. To prevent re-use of the needle, the needle may be permanently locked in its retraced position.

[0030] To prevent user-errors the actuation means for introducing the needle may in an initial condition cover the retraction means, actuation of the actuation means uncovering the retraction means. For example, the actuation means may be in the form of gripping means (e. g. a strip) which is removed from the device, whereby removal triggers needle insertion and at the same time uncovers the retraction for withdrawing the needle.

[0031] As described above, the delivery means may be activated and deactivated when the two units are as-

sembled and disassembled, however, the actuation and retraction means may also be used to activate respectively deactivate the delivery means. Just as for the initial connection between the pump and the reservoir, the initial activation of the delivery means may result in electronic control means being activated resulting in start of pumping action, whereas subsequent deactivation will only deactivate the actual pump action, the control means still being active (e.g. counting the time since initial activation of the control means).

[0032] In the above disclosure of the invention the two units have been described primarily as "unitary" units, however, these two "main" units may in case it is deemed desirable be subdivided into further units. For example, the reservoir unit may be provided with an exchangeable control unit, this allowing different types of control units to be connected to the reservoir unit *per se*. e.g. a first type of control unit may provide a single delivery profile, a second control unit may be programmable to thereby modify the delivery pattern, or a control third unit may comprise means allowing the control unit to communicate with external means. In the latter case the control unit may be controlled using a cordless remote control. Correspondingly, the reservoir may be exchangeable allowing different sizes of reservoirs or different types of drugs to be used.

[0033] In a further aspect of the invention, a needle unit as disclosed above is provided, the needle unit being adapted to be used in combination with a reservoir unit as disclosed above. Correspondingly, the invention also provides a reservoir unit as disclosed above, the reservoir unit being adapted to be used in combination with a needle unit as disclosed above. In an exemplary embodiment such a needle unit may be provided with a hollow needle comprising a pointed distal end with an outlet opening and being adapted to penetrate the skin of a subject, and a pointed proximal end with an inlet opening forming a fluid inlet means, the fluid inlet means being adapted to be arranged in fluid communication with a fluid supply. By this arrangement the needle provides a hydraulically stiff fluid communication between the needle inlet and outlet openings (e.g. made from metal), this allowing early occlusion detection by monitoring a pressure build-up upstream of the needle.

[0034] In a yet further aspect, a system is provided comprising a first needle unit and a first reservoir unit as disclosed above in combination with a least one further needle unit or reservoir unit as disclosed above, the further unit(s) having different capabilities than the first units. The different capabilities may relate to any constructional feature of the units, e.g. the type of needle, the type of user-actuatable means, the type of delivery/pump means, or the type of reservoir/drug.

[0035] In the above disclosure the present invention has been described with reference to a drug delivery device, however, the concept of the invention can be regarded as a modular system providing a number of advantages. Thus, the needle unit may also be in the form of a needle sensor and the "reservoir unit" may correspondingly be in the form of a device adapted to transmit and/or process data acquired via the sensor.

[0036] As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs include pharmaceuticals such as peptides, proteins, and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. In the description of the exemplary embodiments reference will be made to the use of insulin. Correspondingly, the term "subcutaneous" infusion is meant to encompass any method of transcutaneous delivery to a subject. Further, the term needle (when not otherwise specified) defines a piercing member adapted to penetrate the skin of a subject.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] In the following the invention will be further described with references to the drawings, wherein

figs. 1-11 shows in perspective views the sequences of use for a first embodiment of a drug delivery device,

fig. 12 shows a further embodiment of a reservoir unit,

fig. 13 shows a perspective view of a further drug delivery device,

fig. 14 shows in an exploded perspective view a drug delivery device substantially corresponding to the type shown in figs. 1-12,

fig. 15 shows in an exploded perspective view a further drug delivery device,

fig. 16 shows a schematic representation of a membrane pump, and

figs. 17A-17D show different expelling means suitable for use with the invention.

[0038] In the figures like structures are identified by like reference numerals.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0039] When in the following terms such as "upper" and "lower", "right" and "left", "horizontal" and "vertical" or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use. The shown figures are schematic representations

for which reason the configuration of the different structures as well as there relative dimensions are intended to serve illustrative purposes only.

[0040] Firstly, with reference to figs. 1-13 an embodiment of the invention will be described focusing primarily on the directly user-oriented features.

[0041] More specifically, fig. 1 shows a perspective view of medical device in the form of a modular skin-mountable drug delivery device 1 comprising a needle unit 2 and a reservoir unit 5. When supplied to the user each of the units are preferably enclosed in its own sealed package (not shown).

[0042] The needle unit comprises a base portion 10 with a lower mounting surface adapted for application to the skin of a user, and a housing portion 20 in which a hollow infusion needle (not shown) is arranged. The needle comprises a first needle portion having a pointed distal end adapted to penetrate the skin of a user, and a second pointed end adapted to be arranged in fluid communication with the reservoir unit. In the shown embodiment the pointed end of the needle is moveable between an initial position in which the pointed end is retracted relative to the mounting surface, and an extended position in which the pointed end projects relative to the mounting surface. Further, the needle is moveable between the extended position in which the pointed end projects relative to the mounting surface, and a retracted position in which the pointed end is retracted relative to the mounting surface. The needle unit further comprises user-gripable actuation means in the form of a first strip-member 21 for moving the pointed end of the needle between the initial and the second position when the actuation means is actuated, and user-gripable retraction in the form of a second strip-member 22 means for moving the pointed end of the needle between the extended and the retracted position when the retraction means is actuated. As can be seen, the second strip is initially covered by the first strip. The housing further comprises user-actuatable male coupling means 40 in the form of a pair of resiliently arranged hook members adapted to cooperate with corresponding female coupling means on the reservoir unit, this allowing the reservoir unit to be releasable secured to the needle unit in the situation of use. In the shown embodiment the base portion comprises a relatively rigid upper portion 11 attached to a more flexible adhesive patch member 12 having a lower adhesive surface providing the mounting surface *per se*, the adhesive surface being supplied with a peelable protective sheet. The base portion also comprises a ridge member 13 adapted to engage a corresponding groove on the reservoir unit.

[0043] The reservoir unit 5 comprises a pre-filled reservoir containing a liquid drug formulation (e.g. insulin) and expelling means in the form of an electronically controlled pump for expelling the drug from the reservoir through the needle in a situation of use. The reservoir unit has a generally flat lower surface adapted to be mounted onto the upper surface of the base portion, and comprises a protruding portion 50 adapted to be received in a corresponding cavity of the housing portion 20 as well as female coupling means 51 adapted to engage the corresponding hook members 31 on the needle unit. The protruding portion provides the interface between the two units and comprises a pump outlet and contact means (not shown) allowing the pump to be started as the two units are assembled. The lower surface also comprises a window (not to be seen) allowing the user to visually control the contents of the reservoir.

[0044] First step in the mounting procedure is to assemble the two units by simply sliding the reservoir unit into engagement with the needle unit (fig. 2). When the hook members properly engage the reservoir unit a "click" sound is heard (fig. 3) signalling to the user that the two units have been properly assembled. If desired, a visual or audible signal may also be generated. Thereafter the user removes the peelable sheet 14 to uncover the adhesive surface (fig. 4) where after the device can be attached to a skin surface of the user, typically the abdomen (fig. 5). Infusion of drug is started by gripping and pulling away the actuation strip 21 as indicated by the arrow whereby the needle is inserted followed by automatic start of the infusion (fig. 6). The needle insertion mechanism may be supplied in a pre-stressed and subsequently released by the actuation means or the needle insertion may be "energized" by the user. A "beep" signal confirms that the device is operating and drug is infused. The reservoir unit is preferably provided with signal means and detection means providing the user with an audible alarm signal in case of e.g. occlusion, pump failure or end of content.

[0045] After the device has been left in place for the recommended period of time for use of the needle unit (e.g. 48 hours) - or in case the reservoir runs empty or for other reasons - it is removed from the skin by gripping (fig. 7) and pulling (fig. 8) the retraction strip 22 as indicated by the arrows which leads to retraction of the needle followed by automatic stop of drug infusion where after the strip which is attached to the adhesive patch is used to remove the device from the skin surface (fig. 9).

[0046] When the device has been removed the two units are disengaged by simultaneously depressing the two hook members 31 as indicated by the arrows (fig. 10) allowing the reservoir unit 5 to be pulled out of engagement with the needle unit 2 as indicated by the arrow (fig. 11) which can then be discarded. Thereafter the reservoir unit can be used again with fresh needle units until it has been emptied.

[0047] The reservoir unit may be supplied with a fixed basal infusion rate or it may be supplied as an adjustable unit (fig. 12) with adjustment means 55 allowing the infusion rate to be set by a physician and/or the user/patient. The reservoir unit may also be provided with means allowing the control means to be programmed or set electronically (not shown).

[0048] The device described with reference to figs. 1-11 may also be used in alternative ways. For example,

the needle unit may be mounted to the skin after which the reservoir is attached. Depending on the configuration of the needle unit, it may be possible or prevented that the needle is introduced before the reservoir unit is attached.

[0049] In fig. 13 an embodiment of a device adapted for the latter mounting procedure is shown (i.e. mounting the needle unit first).

[0050] More specifically, fig. 13 shows a perspective view of medical device in the form of a drug delivery device 100 comprising a needle housing 110, a base member 130 with a lower mounting surface 133 adapted for application to the skin of the subject, and a separate pump unit 150. In the shown embodiment the base member comprises a relatively rigid upper portion 131 attached to a more flexible adhesive patch member 132 having a lower adhesive surface providing the mounting surface *per se*. The needle housing may be formed integrally with the base member or attached thereto as a separate unit, the two elements in combination forming a platform unit. In the shown embodiment the needle unit comprises a housing 111 within which a hollow needle 112 is pivotally arranged.

[0051] The housing comprises first and second openings (or windows) covered by first and second cover means. In the shown embodiment the first cover means is in the form of a needle penetratable rubber membrane 121 and the second cover membrane is in the form of a breakable paper sheet allowing components to be introduced into the interior of the housing. The paper sheet is penetratable to sterilizing gases, the paper sheet, the rubber membrane and the housing in combination providing a sterility barrier for the encapsulated needle portion.

[0052] The needle comprises a first needle portion 113 having a first pointed end adapted to penetrate the skin of the subject, the first needle portion extending generally perpendicular to the mounting surface, and a second needle portion 114 in fluid communication with the first needle portion via an intermediate needle portion 115 and having a second pointed end, the second needle portion being arranged substantially in parallel with the mounting surface. The needle is connected to the housing by a mounting member 117 allowing the needle to pivot corresponding to an axis defined by the second needle portion, whereby the needle is moveable between an initial sterile position in which the first needle portion is retracted relative to the mounting surface, and a second position in which the pointed end of the first needle portion projects through the rubber septum and relative to the mounting surface. The housing also comprises a biasing member 118 biasing the needle towards the initial position. Often, the "downstream" portion of a needle (here: the first portion) is referred to as the distal portion, and the "upstream" portion of a needle (here: the second portion) is referred to as the proximal portion.

[0053] The reservoir (or pump) unit 150 comprises a housing in which a reservoir and expelling means are arranged. The reservoir is adapted to contain a liquid drug (e.g. prefilled or adapted to be filled by a user) and comprises an outlet means in the form of a protruding needle penetratable septum 155 adapted to be arranged in fluid communication with the second needle portion. The expelling means (not shown) is adapted for in a situation of use to expel a drug out of the reservoir and through the skin of the subject via the hollow needle. The pump unit further comprises a ramp member 156 arranged next to the reservoir outlet.

[0054] The reservoir and expelling means may be of any suitable configuration, e.g. as disclosed with reference to figs. 17A-17D.

[0055] The mounting platform comprises a receiving portion, the receiving portion and the pump unit comprising mating coupling means 160 allowing the pump unit to be secured to the platform unit. The mating coupling means may be releasable allowing a durable or multi-use pump unit to be attached a number of times to a disposable platform unit.

[0056] In a situation of use, the platform unit is mounted on the skin of a user (e.g. by adhesive means arranged on the mounting surface) and the pump unit is attached and locked to the platform unit by sliding it into engagement therewith substantially in parallel with the mounting surface. During the latter operation the protruding septum and the ramp member is moved into engagement with the needle, thereby breaking the paper barrier cover 122, during which operation fluid communication is established between the second needle portion and the reservoir, just as the needle is pivoted from its initial to its second position, the first pointed needle end thereby penetrating the rubber membrane and the skin of the user.

[0057] After the pump unit has been connected and the needle introduced subcutaneously, the pump can be started. This may happen either automatically as the two units are connected or by separate user-actuatable starting means, e.g. a start button (not shown).

[0058] In an alternative embodiment (not shown), the second needle portion may be fixedly (i.e. non-rotationally) attached to the mounting member 117, the intermediate needle portion 115 being elastically bend as it is forced downwardly by the ramp member 156. In such an arrangement the biasing member 118 may be dispensed with.

[0059] Next, with reference to fig. 14, an example of a principle configuration for a delivery device of the type shown in figs. 1-12 will be described. The different components shown in the figures are not drawn to scale just as the outer configuration of the two units are slightly different from the above shown.

[0060] More specifically, fig. 14 shows in an exploded perspective view a medical device in the form of a drug delivery device 200 comprising a needle unit 210 having a needle housing 211, a base member 230 with a lower mounting surface adapted for application to the skin of a subject, and a separate reservoir and pump unit 250.

In the shown embodiment the base member comprises a relatively rigid upper portion 231 attached to a more flexible adhesive patch member 232 provided with a gripable strip and having a lower adhesive surface providing the mounting surface *per se*. In the shown embodiment the needle housing is attached to the base plate as a separate unit, the two elements in combination forming the needle unit. Within the housing a hollow infusion needle 212 is pivotally arranged.

[0061] The needle unit comprises first and second openings 213, 214 which may be open or covered by needle penetratable membranes as described above with reference to fig. 13. The needle also has the same general configuration and pivotable arrangement as described above. The housing further comprises actuation means (not shown) for moving the needle between a retracted and extended state, and retraction means (not shown) for moving the needle between the extended and a retracted position. The actuation and retraction means are actuated by gripable first and second strip members 221, 222 connected to the respective means through slot-formed openings in the housing, of which the slot 223 for the first strip can be seen. The second strip is further connected to the patch strip 233. Arranged on the housing is user-actuatable male coupling means 240 in the form of a pair of resiliently arranged hook members adapted to cooperate with corresponding female coupling means 255 on the reservoir unit. The housing further comprises connecting means 225 for establishing fluid communication between the pump unit and the reservoir (see below), and communication means 226 for activating and de-activating the expelling means.

[0062] The reservoir unit 250 comprises a housing 251 in which a reservoir and expelling means are arranged, the expelling means comprising a pump unit 270 and control and actuation means 280 therefore. The reservoir 260 is in the form of prefilled, flexible and collapsible pouch comprising a needle-penetratable septum 261 adapted to be arranged in fluid communication with the pump unit via pump inlet means 272. The housing comprises a window 252 allowing the user to inspect the content of the reservoir. The shown pump is a mechanically actuated membrane pump, however, the reservoir and expelling means may be of any suitable configuration, e.g. as disclosed with reference to figs. 17A-17D.

[0063] The control and actuation means, which may be arranged on a PCB or flex-print, comprises a pump actuating member 281 in the form of a lever and piston arrangement driven by a coil actuator 282, a microprocessor 283 for controlling, among other, the pump actuation, a contact switch 284 cooperating with the communication means 226 on the needle unit, signal generating means 285 for generating an audible and/or tactile signal, and an energy source 286.

[0064] In fig. 15 is shown an alternative configuration of a drug delivery device 400. The device has the same general construction as the embodiment of fig. 14 and comprises a needle unit 410 having a needle housing 411 in which a needle 412 is pivoting arranged. In contrast to the above-described embodiment, the actuation means is in the form of a user-actuatable lever 421 and the retraction means is in the form of a button 422. Advantageously, the lever cannot be depressed before the reservoir unit is mounted in the needle unit, whereby actuation of the actuation means locks the two units together and actuation of the retraction means releases the two units.

[0065] The reservoir unit 450 comprises a housing 451 in which a flexible reservoir 460, a pump unit 470 in the form of a mechanically actuated membrane pump, and control and actuation means therefore is arranged. The housing comprises a window 452 allowing the user to inspect the content of the reservoir. The control and actuation means comprises a pump actuating member in the form of a lever and piston arrangement 481 driven by a coil actuator 482, a microprocessor 483 for controlling, signal generating means 485 for generating an audible and/or tactile signal, and an energy source 486.

[0066] With reference to fig. 16 a pump unit 300 of a type suitable for use with the reservoir unit of figs. 14 and 15 is shown. The pump is a membrane pump comprising a piston-actuated pump membrane with flow-controlled inlet- and outlet-valves. The pump has a general three-layered construction comprising first, second and third members 301, 302, 303 between which are interposed first and second membrane layers 311, 312, whereby the inlet valve and the pump membrane/pump chamber is formed by the first and second members in combination with the first membrane layer, and the outlet valve is formed by the second and third members in combination with the second membrane layer. The pump further comprises an inlet 321 and an outlet 322 as well as a connection opening 323 which are all three covered by respective membranes 331, 332, 333 sealing the interior of the pump in an initial sterile state. The inlet and outlet membranes are self-sealing, needle-penetratable septa (e.g. of a rubber-like material) and the connection membrane is a breakable membrane (e.g. made from paper). A fluid path is formed in the first member between the inlet and the inlet valve, fluid paths between the inlet valve, pump chamber and outlet valve is formed in the second member, and a fluid path between the outlet valve and the outlet is formed in the second member. The pump also comprises a piston 340 for actuating the pump membrane, the piston being driven by external driving means (not shown).

[0067] The pump further comprises a hollow connection needle 350 slidably positioned in a needle chamber 360 arranged behind the connection opening. The needle chamber is formed by the second and third members and comprises an internal septum through which the needle is arranged, the septum being formed by the first membrane layer and provides a seal between the chamber and the flow path. The needle comprises a pointed

distal end 351, a proximal end on which is arranged a piston 352 and an intermediate opening 353 in flow communication with the distal end, the needle and the piston being slidably arranged relative to the internal septum and the chamber, respectively. As appears, the distal end of the needle is arranged outside the chamber protruding into the flow path.

[0068] In a situation of use the reservoir unit is attached to the reservoir unit (see fig. 14) whereby the proximal end of the infusion needle is introduced through the outlet septum 332 of the pump, and the connection member 225 is introduced through the connection membrane 333, thereby pushing the connection needle from its initial position to a position (not shown) in which the distal end is moved through the inlet membrane 331 and further through the needle-penetratable septum 261 of the reservoir, the outlet opening 353 is positioned in the flow path, thereby providing flow communication between the reservoir and the pump inlet.

[0069] As appears, when the two units are disconnected, the infusion needle 212 is withdrawn from the pump unit outlet whereas the connection needle permanently provides flow communication between the pump and the reservoir.

[0070] In the above-described embodiments a delivery device has been described comprising a flexible reservoir in combination with an example of an expelling means. However, the reservoir and the expelling means may be of any type which would be suitable for arrangement within a skin-mountable drug delivery device. Further, as the needle of the present invention also may be in the form of a needle sensor, the interior of the medical device may comprise sensor means adapted to cooperate with the needle sensor.

[0071] In figs. 17A-17E examples of expelling means suitable for use with the present invention are shown schematically, however, these are merely examples, just as the shown arrangement of the individual components not necessarily are suitable for direct application in the above shown delivery devices. More specifically, fig. 17A shows a pump arrangement comprising a drug-containing cartridge 1010 forming a reservoir and having a distal closure member 1011 allowing a needle to be connected, and a piston 1015 slidingly arranged there within, a flexible toothed piston rod 1020 (for example as disclosed in US patent 6,302,869), an electric motor 1030 which via a worm-gear arrangement 1031 drives the piston rod to expel drug from the cartridge, the motor being controlled by control means 1040 and the energy for the control means and the motor being provided by a battery 1050. The pump may be activated when the needle is inserted (by means not shown) or by separate user-actuatable means (not shown) after the inserter has been detached form the delivery device.

[0072] Fig. 17B shows a pump arrangement comprising a drug-containing cartridge 1110 having distal and proximal closure members 1111, 1112, and a piston 1115 slidingly arranged there within, gas generating means 1120 in fluid communication with the interior of the cartridge via conduit 1121 for driving the piston to expel drug from the cartridge, the gas generating means being controlled by control means 1140 and the energy for the control means and the gas generation being provided by a battery 1150. The pump may be activated as indicated above. A detailed disclosure of such gas generating means for a drug delivery device can be found in e.g. US patent 5,858,001.

[0073] Fig. 17C shows a pump arrangement comprising a drug-containing cartridge 1210 having distal and proximal closure members 1211, 1212, and a piston slidingly 1215 arranged there within, an osmotic engine 1220 in fluid communication with the interior of the cartridge via conduit 1221 for driving the piston to expel drug from the cartridge. The osmotic engine comprises a first rigid reservoir 1225 containing a salt-solution and a second collapsible reservoir 1226 containing water, the two reservoirs being separated by a semi-permeable membrane 1227. When supplied to the user, the fluid connection 1228 between the second reservoir and the membrane is closed by a user-severable membrane (e. g. a weak weld) which, when severed, will allow the osmotic process to start as water is drawn from the second reservoir through the membrane and into the first reservoir. The pump may be activated as indicated above. A detailed disclosure of the osmotic drive principle can be found in e.g. US patent 5,169,390.

[0074] Fig. 17D shows a pump arrangement comprising a drug-containing flexible reservoir 1310 arranged within a rigid fluid-filled secondary reservoir 1311 in fluid communication with a primary reservoir 1320 through a conduit 1330 comprising a flow restrictor 1331. The primary reservoir is in the form of a cartridge with a moveable piston 1321 and contains a viscous drive fluid. A spring 1340 is arranged to act on the piston to drive fluid from the first to the second reservoir thereby expelling drug from the flexible reservoir when the latter is connected to an infusion needle (not shown). The flow rate will be determined by the pressure generated by the spring in the drive fluid, the viscosity of the drive fluid and the flow resistance in the flow restrictor (i.e. bleeding hole principle). The pump may be activated by straining the spring or by releasing a pre-stressed spring, either when the needle is inserted (by means not shown) or by separate user-actuatable means (not shown) after the inserter has been detached from the delivery device. An example of this principle used for drug infusion is known from DE 25 52 446. In an alternative configuration, the drug reservoir may be pressurized directly to expel the drug via a flow restrictor, e.g. as disclosed in US patent 6,074,369.

[0075] In alternative embodiments (not shown) the first needle portion may be in the form of a (relatively soft) infusion cannula (e.g. Teflon ® cannula) and a therethrough arranged removable insertion needle. This type of cannula needle arrangement is well known from so-called infusion sets, such infusion sets typically being

used to provide an infusion site in combination with (durable) infusion pumps.

[0076] In the above description of the preferred embodiments, the different structures and means providing the described functionality for the different components have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

Claims

1. A medical device (1, 100, 200, 400), comprising a needle unit (210) and a reservoir unit (250), the needle unit comprising:

   - a needle (212) comprising a pointed end adapted to penetrate the skin of a subject,
   - a mounting surface adapted for application to the skin of the subject,

   the reservoir unit comprising:

   - a reservoir (260) adapted to contain a fluid drug and comprising an outlet means (261) allowing the needle to be arranged in fluid communication with an interior of the reservoir,
   - expelling means (270) for, in a situation of use, expelling a fluid drug out of the reservoir and through the skin of the subject via the pointed end, and
   - wherein the needle unit and the reservoir unit further comprise releasable mating coupling means (240, 255) allowing the reservoir unit to be secured to the needle unit in the situation of use.

2. A medical device as defined in claim 1, wherein fluid communication between the needle and the reservoir is established when the needle unit and the reservoir unit are secured to each other.

3. A medical device as defined in any of the previous claims, wherein the expelling means is activated when the needle unit and the reservoir unit are secured to each other and de-activated when the units are released from each other.

4. A medical device as defined in any of the previous claims, wherein the expelling means comprises a pump having an inlet means (272, 321) adapted to be arranged in fluid communication with the outlet means of the reservoir, and an outlet means (322) adapted to be arranged in fluid communication with the needle, thereby allowing the needle to be arranged in fluid communication with the interior of the reservoir.

5. A medical device as defined in claim 4, wherein the pump comprises an internal flow path arranged between the inlet and outlet means, the inlet and outlet means sealing the interior of the pump and thereby the flow path in an initial sterile state.

6. A medical device as defined in claim 5, wherein the reservoir unit is transformable from an initial condition in which there is no fluid communication between the pump and the reservoir to a non-reversible operating condition in which fluid communication is established between the inlet means of the pump and the outlet means of the reservoir when the pump unit is secured to a needle unit for the first time.

7. A medical device as defined in claim 6, wherein a connection needle (350) is arranged within the interior of the pump in the initial condition, the needle comprising a pointed inlet end (351) and an outlet (353), the inlet means of the pump and the outlet means of the reservoir being in the form of needle-penetratable septa (331, 261), whereby the connection needle is arranged to be moved between the initial condition and to an operating condition in which fluid communication is established between the interior of the reservoir and the interior of the pump via the connection needle and with the outlet of the connection needle being arranged in the flow path.

8. A medical device as defined in any of the previous claims, wherein the pointed end of the needle is moveable between an initial position in which the pointed end is retracted relative to the mounting surface, and an extended position in which the pointed end projects relative to the mounting surface.

9. A medical device as defined in claim 8, wherein the needle unit comprises actuation means (221) for moving the pointed end of the needle between the initial and the second position when the actuation means is actuated.

10. A medical device as defined in claim 9, wherein the needle unit comprises means for blocking the actuation means, the blocking means being released when the needle unit and the reservoir unit are secured to each other, thereby allowing the actuation means to be actuated.

11. A medical device as defined in claim 9, wherein the expelling means is activated when the actuation means is actuated.

12. A medical device as defined in any of claims 8-11, wherein the pointed end of the needle is moveable between the extended position in which the pointed end projects relative to the mounting surface, and a retracted position in which the pointed end is retracted relative to the mounting surface.

13. A medical device as defined in claim 12, further comprising retraction means (222) for moving the pointed end of the needle between the extended and the retracted position when the retraction means is actuated.

14. A medical device as defined in claim 13, wherein the actuation means in an initial condition covers the retraction means, actuation of the actuation means uncovering the retraction means.

15. A medical device as defined in claim 13, wherein the expelling means is activated when the actuation means is actuated.

16. A medical device as defined in claim 4 and any claim dependent thereto, wherein the needle comprises a first needle portion having the pointed end, and a second needle portion in fluid communication with the first needle portion and having a second end.

17. A medical device as defined in claim 16, wherein the second end of the needle is pointed, the outlet means of the pump comprising a needle-penetratable septum (332) allowing a fluid communication to be established between the second end of the needle and the interior of the pump.

18. A medical device as defined in any of the previous claims, wherein the mounting surface comprises adhesive means allowing the medical device to be attached to a skin surface of the subject.

19. A medical device as defined in claim 18, wherein operation of the retraction means (222) from a first to an intermediate condition causes the needle to be moved from the extended position to the retracted position, and operation of the retraction means from the intermediate to a second condition causes release of the device from the skin surface.

20. A needle device (210), comprising:

- a hollow needle (212) comprising a pointed distal end with an outlet opening and being adapted to penetrate the skin of a subject, and a pointed proximal end with an inlet opening forming a fluid inlet means, the fluid inlet means being adapted to be arranged in fluid communication with a fluid supply, the needle thereby providing an hydraulically stiff fluid communication between the needle inlet and outlet openings, and
- a mounting surface adapted for application to the skin of the subject.

21. A needle device as defined in claim 20, wherein the pointed end of the needle is moveable between an initial position in which the pointed end is retracted relative to the mounting surface, and an extended position in which the pointed end projects relative to the mounting surface, wherein the needle unit preferably comprises actuation means for moving the pointed end of the needle between the initial and the second position when the actuation means is actuated.

Fig. 1

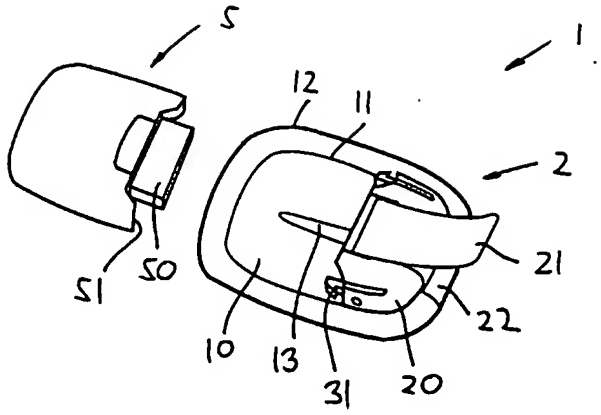

Fig. 2

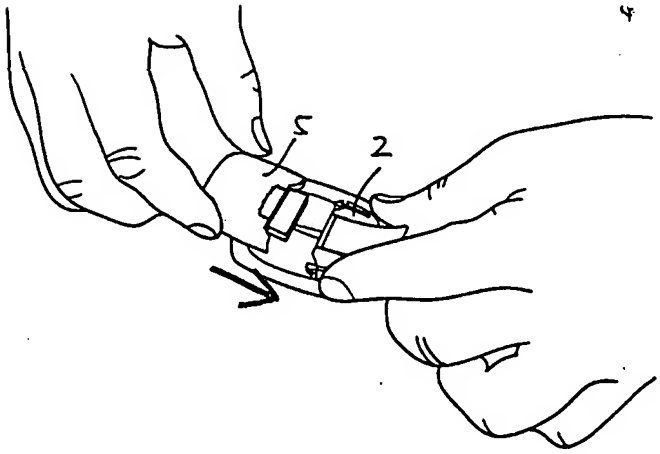

Fig. 3

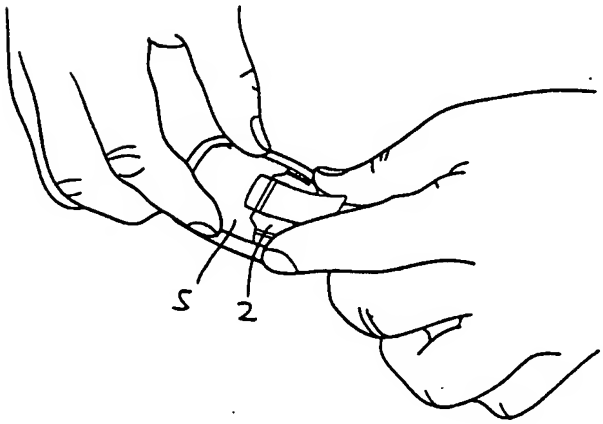

Fig. 4

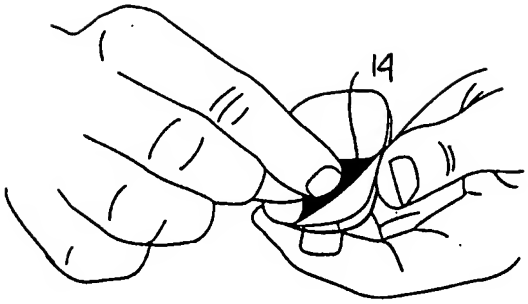

Fig. 5

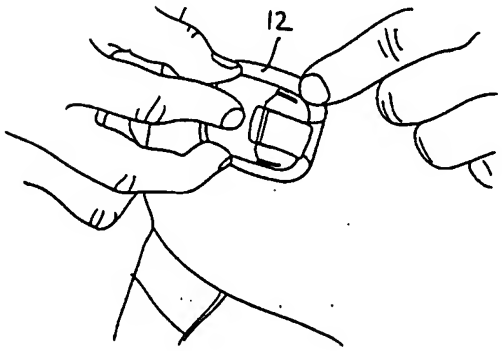

Fig. 6

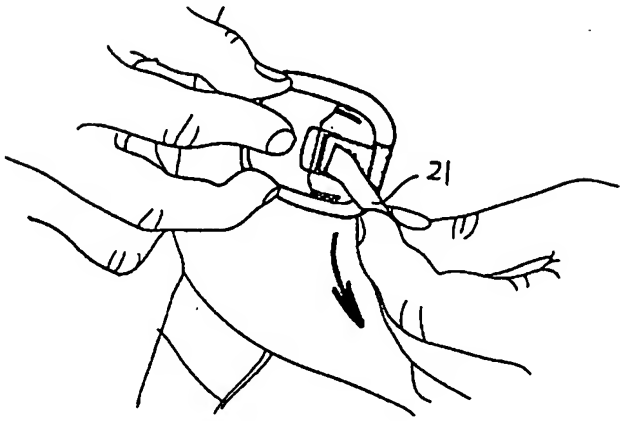

Fig. 7

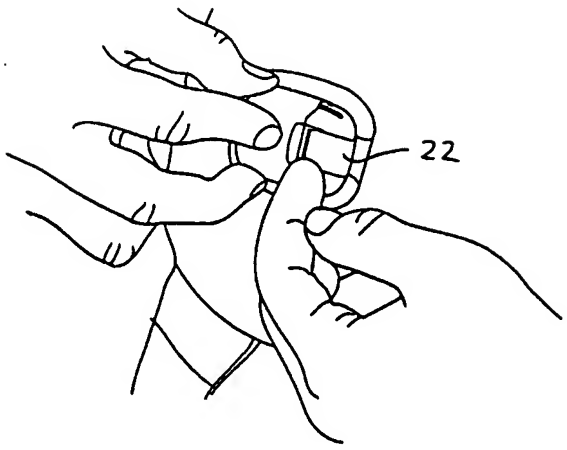

Fig. 8

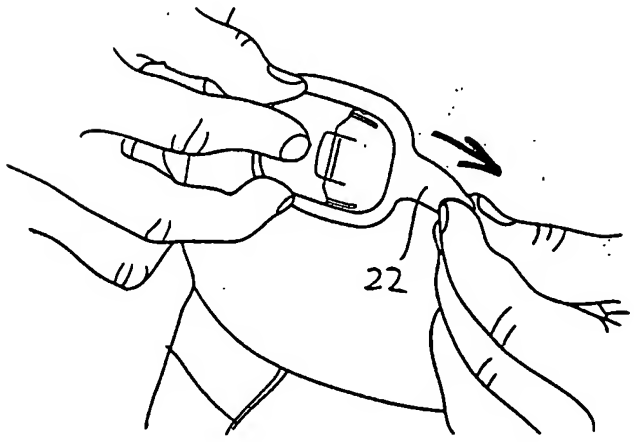

Fig. 9

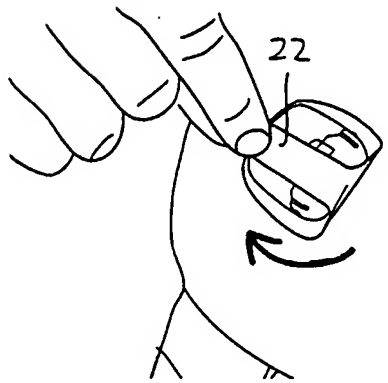

Fig. 10

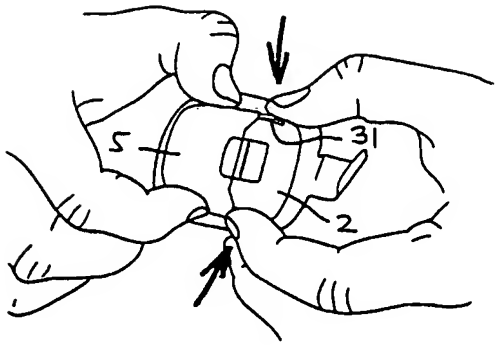

Fig. 11

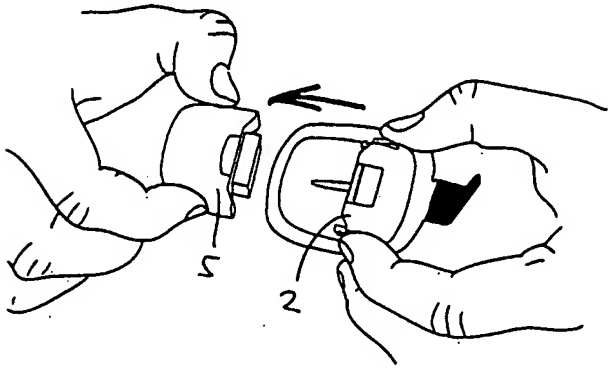

Fig. 12

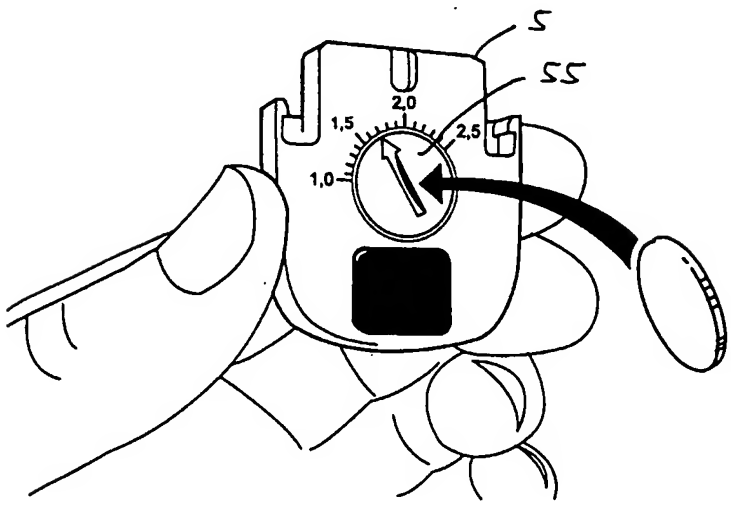

Fig. 13

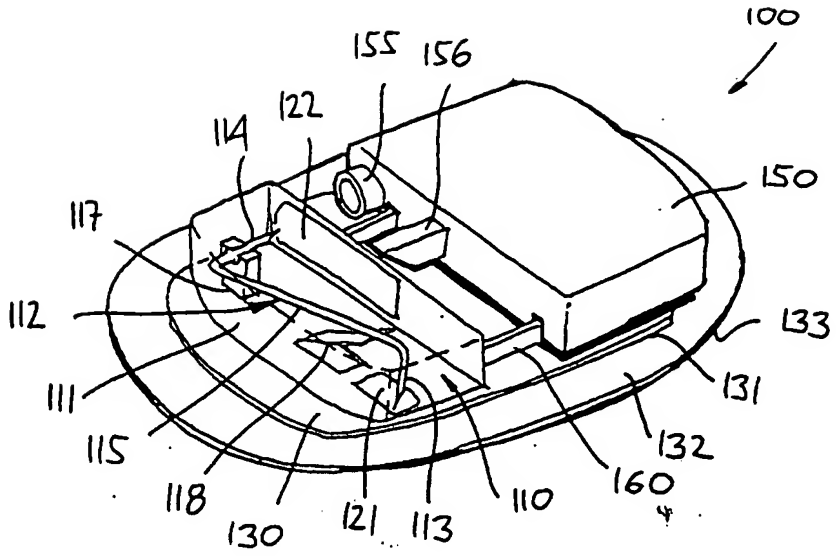
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Fig. 14

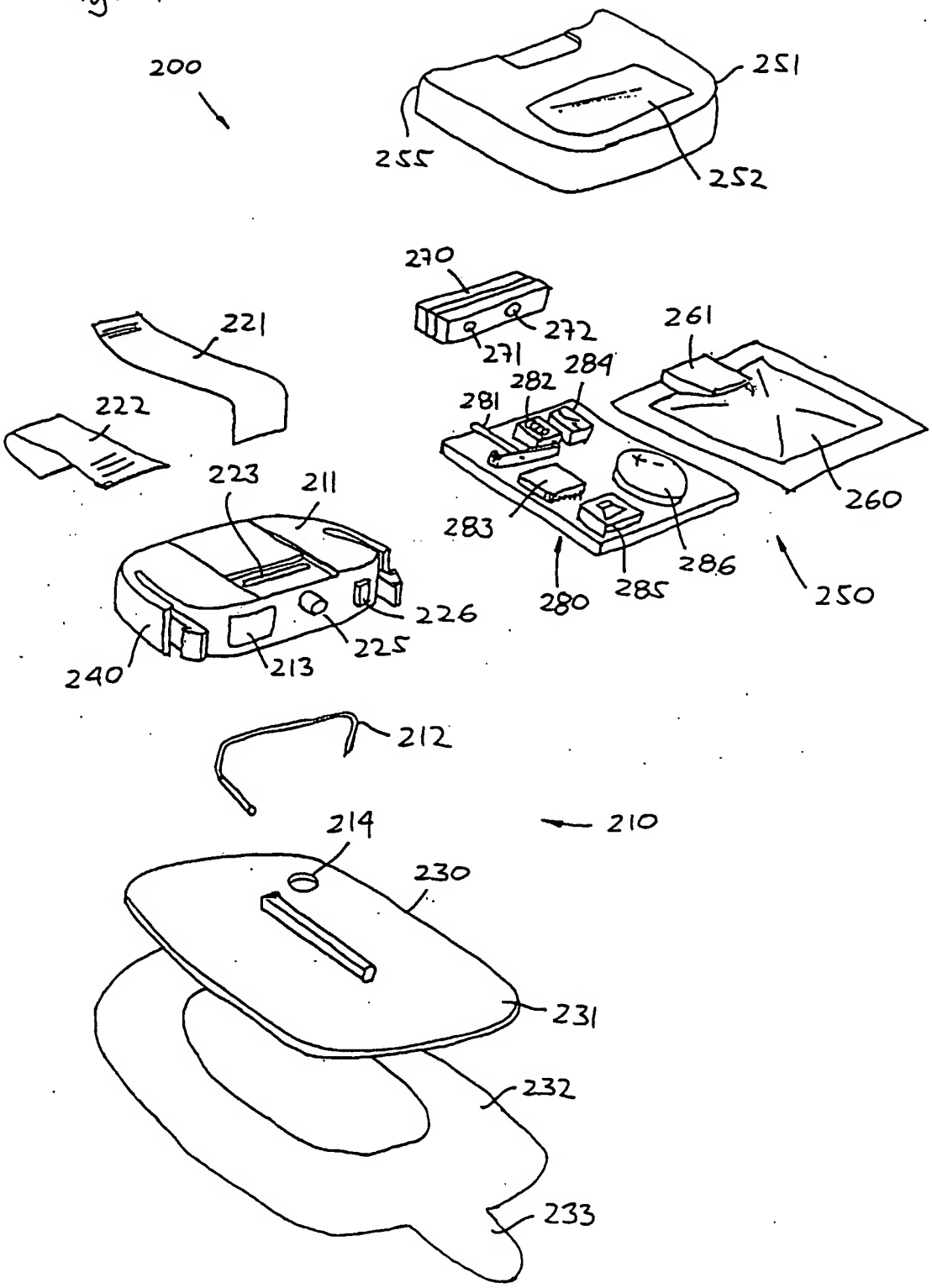
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Fig. 15

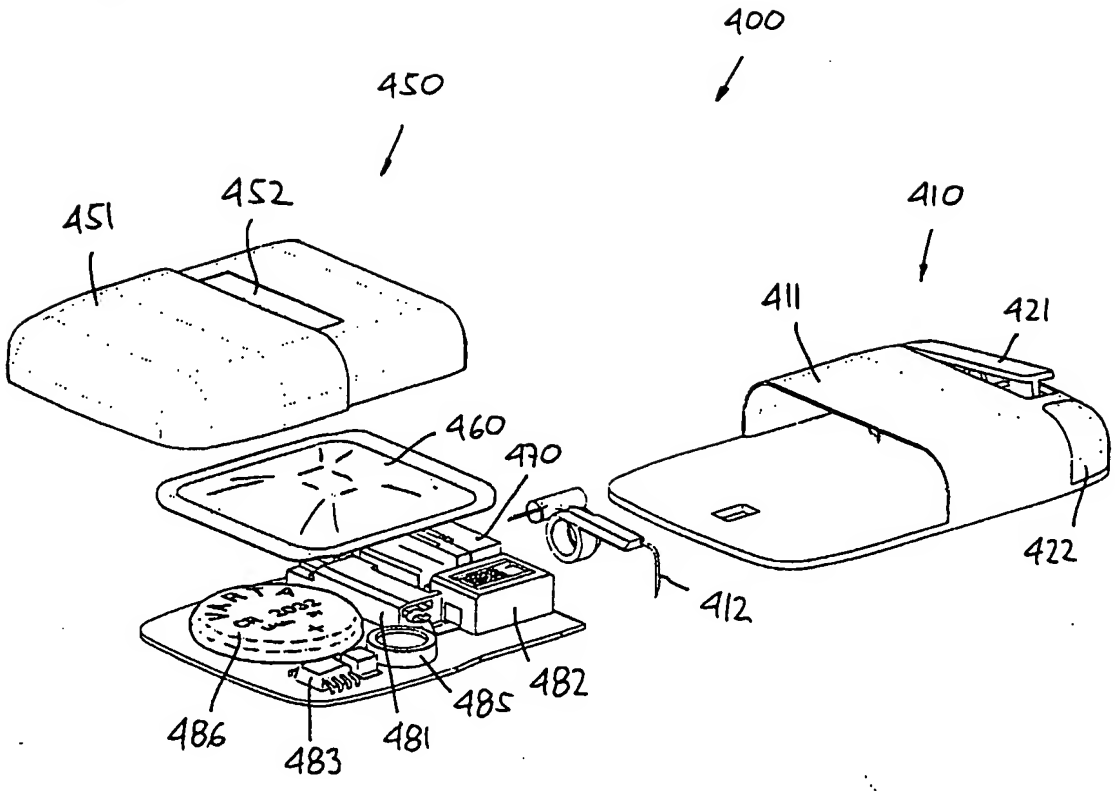

Fig. 16

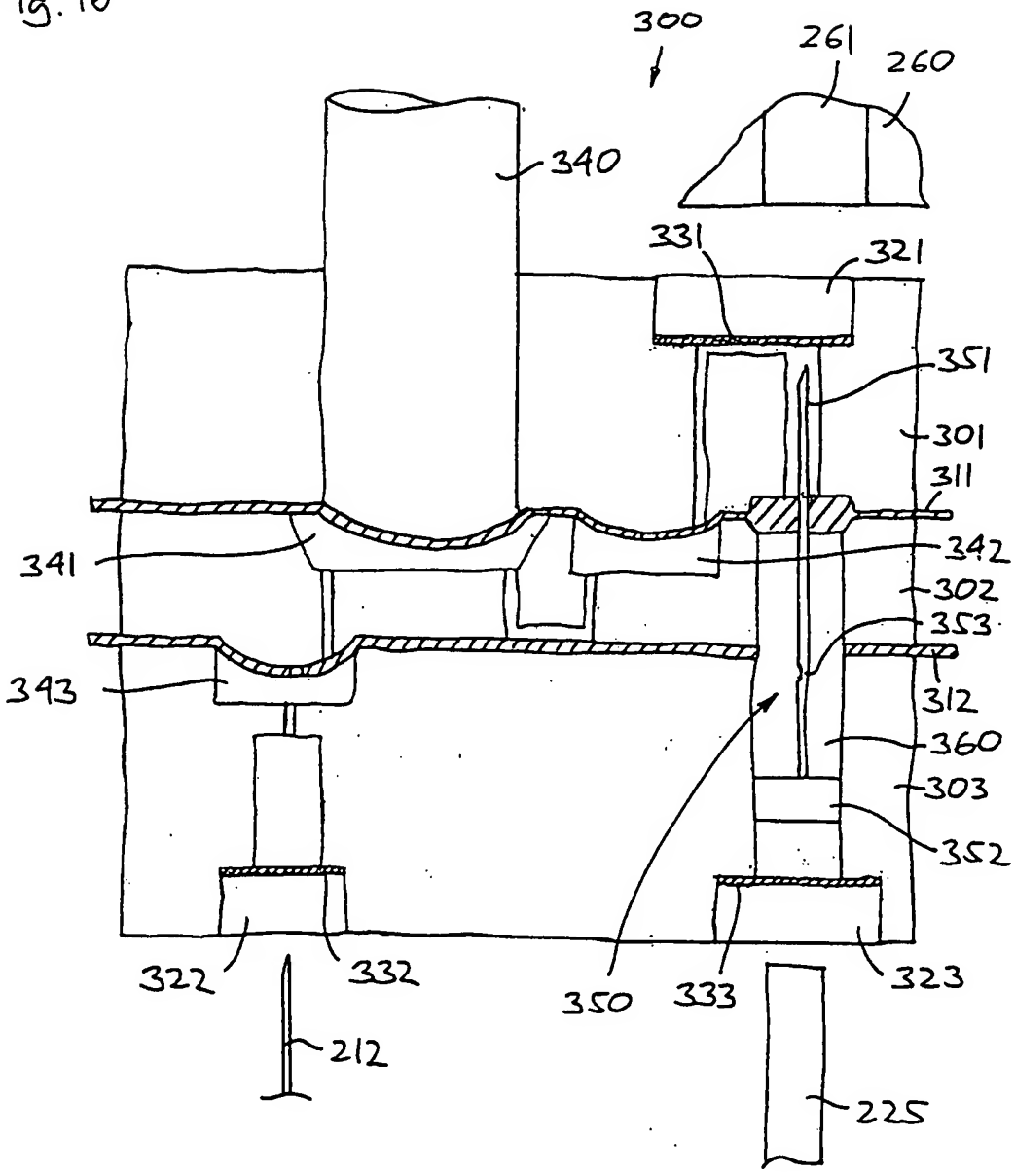
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Fig.17A

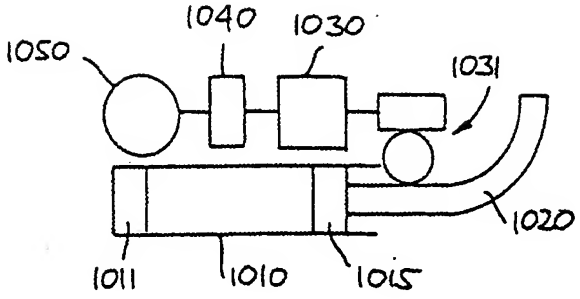


Fig.17B

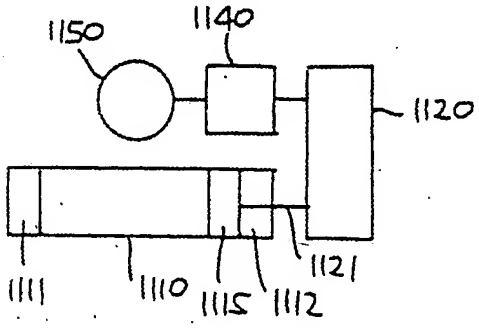


Fig.17C

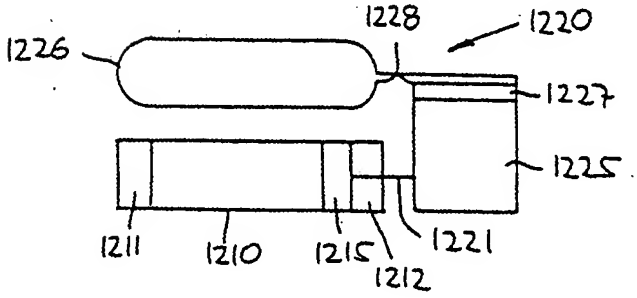
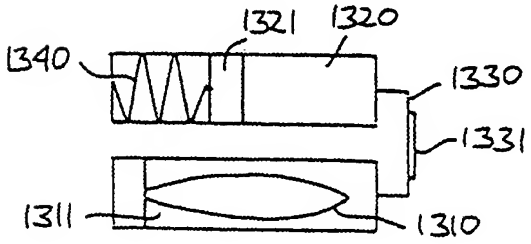


Fig.17D



European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 03 02 4626

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X Y	US 6 364 865 B1 (GROSS JOSEPH ET AL) 2 April 2002 (2002-04-02) * column 3, line 18 - line 37 * * column 10, line 38 - column 11, line 36 * * column 16, line 43 - line 56 * * column 19, line 25 - line 45; figures 4A-C,13A-14,18A-19B *	1,8,9, 11-13, 15,20,21 4-7,10, 16-18	A61M5/142
X A	US 2002/169416 A1 (GONNELLI ROBERT R ET AL) 14 November 2002 (2002-11-14) * paragraph [0004] - paragraph [0013] * * paragraph [0080] - paragraph [0085]; figures 1-3 *	20,21 1-19	
Y	WO 92 22338 A (BADER & PARTNER MEDIZINTECHNIK) 23 December 1992 (1992-12-23) * abstract; figures 4-7 *	4-7,16, 17	TECHNICAL FIELDS SEARCHED (Int.Cl.7)
Y	US 6 500 150 B1 (LAVI GILAD ET AL) 31 December 2002 (2002-12-31) * abstract; figure 3 *	10,18	A61M A61J
A	WO 03 026726 A (NOVO NORDISK AS) 3 April 2003 (2003-04-03) * page 6, line 24 - line 30 * * page 9, line 1 - line 13 * * page 9, line 32 - page 10, line 29 * * page 14, line 32 - page 15, line 3 * * page 15, line 16 - line 21 * * page 18, line 13 - line 21 * * page 26, line 32 - page 27, line 11 *	1-19	
A,D	US 5 858 001 A (GROSS JOSEPH ET AL) 12 January 1999 (1999-01-12)		

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	23 March 2004	Michels, N

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 03 02 4626

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23-03-2004

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